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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,821	03/29/2001	Andrew A. Welcher	01017/36938A	6210

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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05/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/821,821	Applicant(s) WELCHER ET AL.	
	Examiner Prema M. Mertz	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,10,51-55,70,72,74 and 75 is/are pending in the application.
- 4a) Of the above claim(s) 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8, 10, 51-55, 70, 72, 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Previous claims 1, 4-8, 10, 51-55, 70, 72, and new claims 74-75 (3/27/2007) are pending and under consideration by the Examiner. Claims 73 has been canceled in the amendment filed 3/27/2007.
2. Claims 1, 4-8, 10, 51-55, 70, 72, 74, are under consideration by the Examiner.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 3/27/2007:
 - (i) the rejection of claim 73 under 35 U.S.C. 112, second paragraph because the claim has been canceled.
4. Receipt of applicant's arguments and amendments filed on 3/27/2007 is acknowledged.
5. Applicant's arguments filed on 3/27/2007 have been fully considered and were non-persuasive. The issues remaining are stated below.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 U.S.C. 101/35 U.S.C. 112, first paragraph

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1646

7a. Claims 1, 4-8, 10, 51-55, 70, 72, 74, are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (Paper No. 8, 10/15/02), pages 3-9 of the previous Office action (12/4/03), pages 2-4 of the previous Office action (7/13/2004), pages 2-7 of the previous Office action (3/14/2005) and pages 2-8 of the previous Office action (10/13/2005) and pages 2-7 of the previous Office action (6/6/06).

Applicants argue that a person having ordinary skill in the art would have recognized a specific and substantial biological role for a novel testis-specific protein because a testis-specific protein is useful as a tissue-specific marker for detecting testis cells which have moved outside of the testis, either as a micrometastatic deposit of cells into the lymph nodes or bone marrow, or as a secretion into the bloodstream to indicate the presence of an abnormal condition of the testis, such as metastasized testicular cancer. Applicants also argue that tissue-specific markers are not specifically related to cancer necessarily, but elevated levels of a tissue-specific mRNA or protein are useful for identifying a specific tissue as being at fault or suspect and have cited prostate-specific antigen (PSA) as a protein which is preferentially expressed in the prostate and has proven to be a very useful human tissue-specific marker for detecting prostate abnormalities, either as an indicator of prostate cells which have moved outside of the prostate as a tumor (i.e., metastatic prostate cancer) or as an elevated level of PSA in the bloodstream, which can indicate the presence of prostate cancer or benign prostatic hyperplasia (Mulders et al., Eur. J. Surg. Oncol. 16:37-41, 1990). However, contrary to Applicants arguments, Applicants have failed to

Art Unit: 1646

demonstrate differential expression of the instant nucleic acid in other tissues to indicate the presence of an abnormal condition of the testis, such as metastatized testicular cancer to detect testis cells which have moved outside of the testis, either as a micrometastatic deposit of cells into the lymph nodes or bone marrow.

With respect to Applicants arguments regarding PSA, differential expression of PSA in normal and prostate tissue has been demonstrated and elevated PSA expression is well known in the art as being a marker for prostate abnormalities. Furthermore, Applicants arguments are non-persuasive because they are not based on expression of the protein encoded by the claimed nucleic acid or on characteristics of the encoded protein itself to substantiate tissue-specific expression of the claimed nucleic acid.

Applicants argue that differential expression does not need to be shown to establish the utility of agp-96614-al as a marker for testicular cells and that a tissue-specific marker is useful in simply signaling that the testicular cell or protein is being disseminated outside of the testis. Applicants also argue that the marker's usefulness is not solely based on differential expression or exclusive expression in cancer tissue and that an assertion of utility of agp-96614-al as a marker for disseminated testicular cells is not dependent on a differential level of expression of agp-96614-al in cancerous versus healthy cells of the testis because the marker, agp-96614-al, is useful for its ability to identify a testicular cell. However, contrary to Applicants arguments, Applicants have failed to demonstrate the presence of the agp-96614-al marker in other tissues to demonstrate metastatized testicular cancer. Contrary to Applicants arguments, identification of testicular cells in a body location other than in the testis would not be recognized by one of ordinary skill in the art as the identification of a cancerous testicular cell that had metastasized

Art Unit: 1646

because Applicants have failed to show the level of expression of the agp-96614-a1 marker in other tissues to demonstrate metastasized testicular cancer. Therefore, the asserted utility does require a detectable difference of the agp-96614-a1 marker in other tissues to establish micrometastatic deposit of testis cells into the lymph nodes or bone marrow to indicate the presence of an abnormal condition of the testis.

Applicants argue that three later publications identified the exact same molecule (i.e., agp-96614-a1) as being a testis-expressed transmembrane 4 protein (Ishibashi et al., *Gene* 264:87-93, 2001; Liang et al., *Genomics* 72:119-127, 2001; Hulett et al., *Biochem. Biophys. Res. Commun.* 280:374-379, 2001) and the instant application disclosed the complete structures of a protein and encoding nucleic acid and showed preferentially elevated expression in testis cells. However, contrary to Applicants arguments, the issue here is not that the instant agp-96614-a1 molecule is a novel testis-specific marker, but that one of skill in the art would have recognized the utility for this marker, which asserted utility was not recited in the disclosure but presented after the utility rejection was made by the Examiner. An implicit disclosure of the use of the claimed subject matter as a marker for testicular cell dissemination or metastasis is not evident in the instant disclosure and therefore the instant disclosure is insufficient under 35 USC 101. Even though the claimed nucleic acid is predominantly expressed in the testis, Applicants have failed to show that the claimed nucleic acid is a marker for a testicular cell and have failed to show the level of the claimed marker in other tissues to indicate that the testis-specific protein has spread to other parts of the body. Applicants have failed to demonstrate that diagnostic information can be obtained by determination of the expression pattern of agp-96614-a1 marker in tissues of the human body.

Art Unit: 1646

Claim rejections-35 U.S.C. 112, first paragraph

7b. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-8, 10, 51-55, 70, 72, 74 are also rejected under 35 U.S.C. 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (Paper No. 8, 10/15/02), pages 3-9 of the previous Office action (12/4/03), pages 2-4 of the previous Office action (7/13/2004), pages 2-7 of the previous Office action (3/14/2005) and pages 2-8 of the previous Office action (10/13/2005) and page 7 of the previous Office action (6/6/06).

Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

No claim is allowed.

Claims 1, 4-8, 10, 51-55, 70, 72, 74 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1646

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
May 1, 2007